REMARKS/ARGUMENTS

Objection Due to Lack of Compliance with the Sequence Rules

Drawings and Specification

The Examiner has objected to the drawings set forth as Figure 1 because the figure depicts an amino acid sequence, which is not identified by sequence identification number, either in the figure or in the brief description of figures on page 12. The Examiner also states that a replacement drawing sheet, including the correction, is required, if the drawings are objected to, in accordance with 37 C.F.R. 1.121(d). However, the Examiner states that "this ground of objection would be withdrawn, so that a replacement drawing would not be required, if Applicant were to amend the brief description of the figure at pages 8 and 10 of the specification to include sequence identification numbers." In response to this objection, Applicants have amended the specification as requested by the Examiner by inserting a sequence identification number on pages 8, 10 and 12 as indicated in the "Amendments to the Specification" section above to identify sequence T128 and Figure 1 as SEQ ID NO: 1.

The Examiner has also objected to the disclosure in the specification in accordance with 37 C.F.R. 1.821(a)(1) and (a)(2), contending that "page 7, line 30 of the specification discloses the amino acid sequence 'MYIGEMLR' without a SEQ ID NO and it appears that this sequence is not listed in the present Sequence Listing." Accordingly the Examiner requires that Applicants must provide amendments to the specification or drawings inserting the required sequence identifiers. For clarification, Applicants respectfully point out that on page 7, line 30, the item at issue is "M*T*IGEMLR" and not "M*Y*IGEMLR" (italics added for emphasis). Applicants also point out that as found on page 7, sequence "MTIGEMLR..." is not itself a sequence but a reference to SEQ ID NO: 1 (as evidenced by the ellipsis following the sequence fragment), and thus does not require a sequence identification number. Nevertheless to render the issue moot, the specification has been amended at page 7, line 30 as indicated in the "Amendments to the Specification" section above by truncating "MTIGEMLR... etc." to "MTI... etc." and thus removing any requirement that the referential sequence be identified by a sequence identifier under 37 C.F.R. § 1.821.

Accordingly, Applicants respectfully request withdrawal of the Examiner's objections that are based on lack of compliance with sequence rules.

Election/Restrictions

The Examiner has issued a restriction requirement under 35 USC §§ 121 and 372, identifying the following fourteen groups, which the Examiner contends are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Group I: claims 1-6, 19, 25, 26 and 30, drawn to isolated nucleic acid molecules

Group II: claims 7-9, 27, 28 and 31, drawn to isolated proteins

Group III: claims 10 and 29, drawn to monoclonal antibodies

Group IV: claims 15-17, insofar as they are drawn to a method of detecting cancer in a patient

Group V: claims 15-17, insofar as they are drawn to a method of monitoring cancer in a patient

Group VI: claim 18, insofar as it is drawn to a method of detecting gastro-intestinal cancer in a patient

Group VII: claim 18, insofar as it is drawn to a method of detecting kidney cancer in a patient

Group VIII: claim 18, insofar as it is drawn to a method of detecting prostate cancer in a patient

Group IX: claim 18, insofar as it is drawn to a method of monitoring gastro-intestinal cancer in a patient

Group X: claim 18, insofar as it is drawn to a method of monitoring kidney cancer in a patient

Group XI: claim 18, insofar as it is drawn to a method of monitoring prostate cancer in a patient

Group XII: claims 20-21 and 24, drawn to a method of prophylaxis or treatment of cancer comprising the step of administering to a patient a pharmaceutically effective amount of a nucleic acid molecule

Group XIII: claim 22, drawn to a method of prophylaxis or treatment of cancer comprising the step of administering to a patient a pharmaceutically effective amount of a protein

Group XIV: claim 23, drawn to a method of prophylaxis or treatment of cancer comprising the step of administering to a patient a pharmaceutically effective amount of an antibody.

The Examiner has indicated that the inventions defined by the delineated Groups lack the same or corresponding special technical feature. Applicants traverse this restriction requirement and consider that the fourteen Groups do possess a common special technical feature for the reasons given below, and request rejoinder of the claim groups.

The Examiner states that the technical feature of claim 1 is nucleic acid molecules encoding SEQ ID NO:1, polypeptides at least 80% identical to SEQ ID NO:1 or a fragment thereof or nucleic acid molecules that specifically hybridize with a nucleic acid molecule encoding SEQ ID NO:1. The Examiner believes that claim 1 lacks inventive step over Lisziewicz et al. (PNAS, 89:11209-11213 (1992)), which teaches degenerate nucleic acid molecules that are 28 base pairs in length that comprise any DNA nucleotide at each position. The Examiner's analyses of the special technical features of each of the other claim groups II-XIV are similar. In response, Applicants do not believe that the disclosure by Lisziewicz et al. can form a basis for rendering obvious any of the instant claims, and therefore those same claims do not lack a special technical feature in common.

Lisziewicz et al. describes development and use of a culture system that simulates in vivo conditions of human immunodeficiency virus type 1 (HIV-1) infection to evaluate long-term efficacy of antisense oligonucleotide treatment. As part of that assay, a "random sequence" of 28 base pairs is prepared as a control. That random sequence is not a sequence at all but instead is a mixture of every possible 28-mer using the four nucleotides G, C, A and T. The "random sequence" is prepared by including in the nucleic acid synthesis a mixture of the four nucleotides G, C, A and T at every coupling step. Thus, the resulting preparation is a mixture of 4^{28}, i.e. more than 70,000,000,000,000,000 different sequences. None of the individual sequences is isolated from the mixture, because Lisziewicz et al. prepares the mixture as a control. Therefore, such an isolation of any nucleotides from the mixture would run contrary to the purpose of Lisziewicz et al. in preparing the "random sequence" in the first place.

As pending, claim 1 of the instant application recites "isolated nucleic acid molecules." Further, claim 1 recites "T120 polypeptide." Because each of claims 2-31 ultimately depends from claim 1, the requirement that the nucleic acid is isolated is required

in all of the claims of the instant application. Therefore, a common special technical feature between all of the claims is at least an isolated T120 polypeptide. Applicants do not believe that the disclosure by Lisziewicz et al. of a mixture of more than 70 quadrillion nucleic acids can be fairly characterized as being isolated, and consequently that reference cannot fairly be characterized as rendering claim 1, or any of claims 2-31, obvious. Accordingly, Applicants believe that there is no basis for the Examiner's assertion that the claims lack a common technical feature, and consequently there is no basis for the restriction requirement. Therefore, Applicants respectfully request that the Examiner remove the restriction requirement, and request rejoinder of all of the claims.

Should the Examiner nevertheless maintain the restriction requirement, despite Applicants' arguments to the contrary, Applicants elect herein Group II (i.e. claims 7-9, 27, 28 and 31, drawn to isolated proteins) pursuant to MPEP § 818.03(b).

CONCLUSION

Applicants believe that the foregoing amendments and remarks are fully responsive to each of the Examiner's objections and requirements. Hence, Applicants respectfully request that the instant application be passed on to examination leading to allowance and issuance.

Respectfully submitted,
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